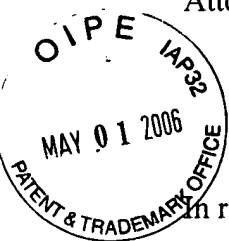




AMENDMENT TRANSMITTAL LETTER				Docket No. 62069DIV2(51590)	
Application No. 10/823,365-Conf. #4859		Filing Date April 13, 2004		Examiner G. W. Mitchell	
Art Unit 1617					
Applicant(s): Gavril W. Pasternak et al.					
Invention: TOPICAL ANESTHETIC/OPIOID FORMULATIONS AND USES THEREOF					
TO THE COMMISSIONER FOR PATENTS					
Transmitted herewith is an amendment in the above-identified application.					
The fee has been calculated and is transmitted as shown below.					
CLAIMS AS AMENDED					
	Claims Remaining After Amendment	Highest Number Previously Paid	Number Extra Claims Present	Rate	
Total Claims	20	- 35 =		x	
Independent Claims	1	- 3 =		x	
Multiple Dependent Claims (check if applicable) <input type="checkbox"/>					
Other fee (please specify):					
TOTAL ADDITIONAL FEE FOR THIS AMENDMENT:					0.00
<input type="checkbox"/> Large Entity <input checked="" type="checkbox"/> Small Entity					
<input checked="" type="checkbox"/> No additional fee is required for this amendment.					
<input type="checkbox"/> Please charge Deposit Account No. _____ in the amount of \$ _____. A duplicate copy of this sheet is enclosed.					
<input type="checkbox"/> A check in the amount of \$ _____ to cover the filing fee is enclosed.					
<input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.					
<input checked="" type="checkbox"/> The Director is hereby authorized to charge and credit Deposit Account No. <u>04-1105</u> as described below. A duplicate copy of this sheet is enclosed.					
<input checked="" type="checkbox"/> Credit any overpayment.					
<input checked="" type="checkbox"/> Charge any additional filing or application processing fees required under 37 CFR 1.16 and 1.17.					
<div style="text-align: center;"><div style="display: flex; justify-content: center; align-items: center;"><div style="text-align: left; margin-right: 10px;">Amy M. Leahy Attorney/Agent Reg. No.: 47,739</div><div>EDWARDS ANGELL PALMER & DODGE LLP P.O. Box 55874 Boston, Massachusetts 02205 (203) 353-6817</div></div></div>				Dated: <u>May 1, 2006</u>	
I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date shown below with sufficient postage as First Class Mail, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.					
Dated: May 1, 2006		Signature: <u>Edith Sillman</u> (Edith Sillman)			



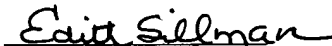
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Pasternak et al. Confirmation No. 4859
U.S. Serial No. 10/823,365 Examiner: Mitchell, Gregory W
Filed: April 13, 2004 Group Art Unit: 1617
For: TOPICAL ANESTHETIC/OPIOID FORMULATIONS AND USES
THEREOF

CERTIFICATE OF EXPRESS MAIL

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service in an envelope addressed to MS Amendment, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 as "Express Mail Post Office to Addressee" Mailing Label No. EV 722914066 US on May 1, 2006.

Date: May 1, 2006


Edith Sillman

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT UNDER 37 C.F.R. § 1.11

Sir:

This paper is submitted in response to the Office Action mailed on November 30, 2006. A Petition for a two-month Extension of Time and a Declaration of the Inventors under 37 C.F.R. § 1.132 accompanies this response.

The listing of the claims begins on page 2.

Remarks begin on page 5.

AMENDMENT

Please amend the claims without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents, as follows

1. - 10. (Cancelled)

11. (Currently Amended) A method of providing topical analgesia to a subject comprising ~~topical administration of~~ topically administering to peripheral sites in the subject a pharmaceutical composition comprising ~~at least two compounds, one effecting opioid analgesia and one effecting local anesthesia, wherein the pharmaceutical composition is administered in (i)~~ synergistically effective amounts of morphine and butamben and (ii) a physiologically acceptable topical excipient, and in an amount and a duration sufficient to potentiate an antinociceptive response to potentiate analgesia at the peripheral sites.

12. – 15. (Cancelled)

16. (Currently Amended) The method according to claim 11, wherein the ~~analgesic pharmaceutical composition contains morphine is administered~~ in a dose of about 0.01% to about 25% of the composition.

17. (Currently Amended) The method according to claim 11, wherein the ~~analgesic pharmaceutical composition contains morphine is administered~~ in a dose of about 0.1% to about 10% of the composition.

18. (Currently Amended) The method according to claim 11, wherein the ~~analgesic pharmaceutical composition contains morphine is administered~~ in a dose of about 0.5% to about 5% of the composition.

19. (Currently Amended) The method according to claim 11, wherein the ~~analgesic pharmaceutical composition contains morphine is administered~~ in a dose of about 0.01% to about 1% of the composition.

20. (Currently Amended) The method according to claim 11, wherein the ~~analgesic~~pharmaceutical composition contains morphine ~~is administered~~ in a dose of about 0.01% to about 0.05% of the composition.

21. (Cancelled)

22. (Currently Amended) The method according to claim 11, wherein the ~~local anesthetic~~pharmaceutical composition contains butamben ~~is administered~~ in a dose of about 0.01% to about 25% of the composition.

23. (Currently Amended) The method according to claim 11, wherein the ~~local anesthetic~~pharmaceutical composition contains butamben ~~is administered~~ in a dose of about 0.1% to about 15% of the composition.

24. (Currently Amended) The method according to claim 11, wherein the ~~local anesthetic~~pharmaceutical composition contains butamben ~~is administered~~ in a dose of about 0.5% to about 5% of the composition.

25. (Currently Amended) The method according to claim 11, wherein the ~~local anesthetic~~pharmaceutical composition contains butamben ~~is administered~~ in a dose of about 0.01% to about 1% of the composition.

26. (Currently Amended) The method according to claim 11, wherein the ~~local anesthetic~~pharmaceutical composition contains butamben ~~is administered~~ in a dose of about 0.01% to about 0.05% of the composition.

27. (Original) The method according to claim 11, wherein the pharmaceutical composition further comprises a tolerance attenuating or preventing NMDA receptor antagonist and wherein the NMDA receptor antagonist is selected from the group consisting of dextromethorphan, dextrorphan, ketamine, pyroloquinoline quinone, cis-4-(phosphonomethyl)-2-piperidine carboxylic acid, MK801, memantine, and their mixtures and pharmaceutically acceptable salts thereof.

28. (Currently Amended) The method according to claim ~~11~~27, wherein the pharmaceutical composition contains the NMDA receptor antagonist ~~is administered~~ in a dose of about 0.01% to about 25% of the composition.

29. (Currently Amended) The method according to claim ~~11~~27, wherein the pharmaceutical composition contains the NMDA receptor antagonist ~~is administered~~ in a dose of about 0.1% to about 15% of the composition.

30. (Currently Amended) The method according to claim ~~11~~27, wherein the pharmaceutical composition contains the NMDA receptor antagonist ~~is administered~~ in a dose of about 0.5% to about 5% of the composition.

31. (Currently Amended) The method according to claim ~~11~~27, wherein the pharmaceutical composition contains the NMDA receptor antagonist ~~is administered~~ in a dose of about 0.01% to about 1% of the composition.

32. (Currently Amended) The method according to claim ~~11~~27, wherein the pharmaceutical composition contains the NMDA receptor antagonist ~~is administered~~ in a dose of about 0.01% to about 0.05% of the composition.

33. (Currently Amended) The method according to claim 11, wherein topical administration of the pharmaceutical composition is ~~directed~~provided to cutaneous, mucosal, vaginal, rectal, ocular, or nasal surfaces.

34. (Original) The method according to claim 11, wherein the pharmaceutical composition is topically administered to a subject in an amount and duration sufficient to prevent or relieve acute and chronic peripheral neuropathy.

35. (Original) The method according to claim 11, wherein the pharmaceutical composition is topically administered to a subject in an amount and duration sufficient to prevent or relieve neuropathic inflammation.